UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,936	05/03/2001	H. Kirk Hammond	220002057125	6165

25226 7590 07/01/2004

MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER	
WEHBE, ANNE MARIE SABRINA	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/847,936	HAMMOND ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-156* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-156* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the restriction/election requirement received on 3/30/04 has been entered. Applicant's election with traverse of the species "FGF-4" as the first angiogenic protein and the species "VEGF-A" as the second angiogenic protein is acknowledged. Applicant's arguments regarding the grounds for species election have been persuasive and the species election has been **withdrawn**. However, upon further consideration by the examiner, new grounds for restriction have been applied.

The following is a requirement for restriction/election under 35 U.S.C. 121.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-36, 40-45, 52-54, 55-100, 104-109, and 116-120, drawn to methods comprising administering a transgene encoding an angiogenic protein or proteins, classified in class 514, subclass 44.

II. Claims 1, 37-39, 57, and 101-103, drawn to methods comprising administering a transgene encoding an angiogenic protein AND a transgene encoding a cardiac enhancing protein or peptide, classified in class 514, subclass 44.

III. Claims 1, 46-51, 57, and 110-115, drawn to methods comprising administering a transgene encoding an angiogenic protein AND infusing an artery with a vasoactive agent, classified in class 514, subclasses 2 and 44.

IV. Claims 121-148 and 151-152, drawn to a vector compositions containing a transgene encoding an angiogenic protein or proteins and a kit comprising the composition, classified in class 435, subclass 320.1.

V. Claims 121, and 149-150, drawn to a vector compositions containing a transgene encoding an angiogenic protein AND a transgene encoding a cardiac enhancing protein or peptide, classified in class 435, subclass 320.1.

VI. Claims 152-154, drawn to kits comprising a vector comprising a transgene encoding an angiogenic protein AND a device for introducing the composition to a blood vessel, classified in class 435 and 604, subclass 320.1 and 508 respectively.

VII. Claims 152, and 155-156, drawn to kits comprising a vector comprising a transgene encoding an angiogenic protein AND a vasoactive agent, classified in classes 435 and 530, subclasses 320.1 and 350 respectively.

Claims 1 and 57 link inventions I-III. Claim 121 links inventions IV and V. Claim 152 links inventions IV, VI, and VII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 57 OR claim 121 OR claim 152. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional

application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:
1) Inventions I-III are patentably distinct each from the other because while each of the inventions shares the step of administering a transgene encoding an angiogenic protein, invention II further comprises administering a transgene encoding a cardiac enhancing protein and invention III further comprises administering a vasoactive agent. These additional steps require the use of substantially different substances, transgenes encoding a cardiac enhancing protein versus a vasoactive agent which is a protein. These substances differ substantially in physical, chemical, and functional properties and have substantially different bioactivity in a subject.
2) Inventions IV-VII are patentably distinct each from the other because the physical, chemical, and functional properties of each kit are substantially different. In particular, while each of the compositions/kits comprises a transgene encoding an angiogenic protein, invention V further comprises a cardiac enhancing protein, invention VI further comprises a device such as a catheter, and invention VII further comprises a vasoactive agent such as histamine. Cardiac enhancing protein, a catheter device, and a vasoactive agent have substantially different structures, physical and chemical properties, and functions.

3) Inventions I-III and IV-VII are generally related as product and process of use. The inventions can be shown to be distinct if *either or both* of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compositions and kits can be used for substantially different purposes than administration to a subject, such as the use of the compositions in *in vitro* assays. Further, the process for using the compositions/kits can be practiced with many different compositions, such as those identified individually in inventions IV-VII which each differ from the other in physical, chemical, and functional properties.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different search requirements and different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, the technology center fax number is (703) 872-9306. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER